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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,384	10/29/2003	Mahesh Chaubal	IFT-5657A-1A1C6	8266

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,384	CHAUBAL ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20,22-26 and 28-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20,22-26 and 28-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants': RCE, amendment, and remarks; all filed on 12 October 2007.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 October 2007 has been entered.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 22, 24, 25, and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2002/1076935 ("Kipp").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Kipp discloses a method for preparing small particles of an organic compound (*see* abstract) comprising:

- the method of instant claims 1, 46, and 49 (*see* paragraph 0017);
- the itraconazole of instant claim 22 (*see* paragraph 0032);
- the carbamazepine of instant claim 24 (*see* example 6);
- the prednisolone of instant claim 25 (*see* example 9);
- the therapeutic agents of instant claim 47 (*see* paragraph 0032); and
- the particle size of instant claim 48 (*see* paragraph 0017).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/1076935 ("Kipp").

Kipp discloses a method for preparing small particles of an organic compound (*see* above).

Kipp explains that the disclosed method is beneficial because it produces stable particles of an organic compound that are suitable for delivery intravenously (*see* paragraph 0017).

Kipp differs from the instant application in that it does not explicitly disclose the budesonide of instant claim 23 and the nabumetone of instant claim 26. However, Kipp discloses the class budesonide belongs to, i.e. steroidal compounds (*see* paragraph 0032), as well as the class of drugs nabumetone belongs to, i.e. non-steroidal anti-inflamatory drugs (*see* paragraph 0032). As such, it would be obvious to a person of ordinary skill in the art to use budesonide and nabumetone in a method for preparing small particles of a poorly water soluble pharmaceutically active compound, since Kipp discloses such a method using the class of drugs said compounds belong to.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 28-48 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. when the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides methods for producing particles of pharmaceutical compounds having a desired particle size and polymorph by seeding solutions or pre-suspensions of the pharmaceutical compound. (2) The state of the prior art

Various methods of producing particles of organic compounds such as pharmaceutical agents using precipitation techniques and seeding are known in the prior art. It is generally known in the prior art that the processing parameters of such methods can be manipulated to achieve desired characteristics of such particles, such as Size, crystal habit, and polymorphic form.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability Or unpredictability of the art

The unpredictability of the art is high, even if the concepts behind particle production of pharmaceutical compounds are known. The particular method steps, in terms of complexity and number of method steps, for the production of particles of a pharmaceutical compound are required to be specifically tailored to the pharmaceutical compound in question, as well as being tailored for the particular set of desired characteristics, such as size and polymorphic form.

(5) The breadth of the claims

The claims are very broad. The methods claims are drawn to methods of producing particles of any poorly water soluble pharmaceutical compound, with no further limitations given on what sort of solvents and surfactants may be specifically used in the instant claims.

(6) The amount of direction or guidance presented

In the instant specification, the applicant has disclosed several types of techniques for precipitations, such as microprecipitation, emulsion precipitation, solvent/anti-solvent precipitation, phase inversion precipitation, pH shift precipitation, infusion precipitation, temperature shift precipitation, solvent evaporation, reaction precipitation, and compressed fluid precipitation. Additional steps such as seeding and the addition of energy are also disclosed. However, aside from those compounds specifically mentioned in the examples, there is no specific guidance within the instant specification as to which techniques or combination of techniques are suitable for a particular pharmaceutical compound or for producing particles having a particular

desired characteristic, such as particle size, range of particle size, or polymorphic form. Thus, there is scant guidance for methods of particle preparation for every conceivable compound that is encompassed by the broad scope of the claims.

(7) The presence or absence of working examples

The instant disclosure does provide working examples, but they are limited to only five pharmaceutical compounds, itraconazole, budesonide, carbamazepine, prednisolone, and nabumetone. Although the particular steps taken to produce the particles of pharmaceutical compounds are described in sufficient detail, there is no further discussion as to why such steps or combination of steps are needed to produce particles with the desired characteristics. One example (Example 15) is described as a prophetic example, discussing possible steps that may be taken to produce a stable polymorph of an unspecified compound. (8) The quantity of experimentation necessary

With the lack of specific guidance from the instant specification, the particular combination of method steps which would be suitable for the production of particles of a particular pharmaceutical compound having a particular set of desired characteristics encompassed within the instantly claimed invention cannot be reliably predicted a priori. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the proper method steps for each and every pharmaceutical compound that is encompassed within the scope of the instant claims.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618